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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, DAVE TRONG	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/654,223	Applicant(s) DEDIEU ET AL.	
	Examiner Dave Nguyen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

The information under CFR 1.56 filed May 11, 2001 has been considered by the examiner in accordance with MPEP1448, 2010 and 2012, and is not found relevant to the patentablity of the claimed invention. Therefore, no further action from the office is warranted with respect to the information under CFR 1.56 filed May 11, 2001.

The drawings are objected because the submitted drawings for this as-filed reissue application still contain information and/or references to the US '531 patent. A **complete response to this office action must include a response to the objection or a filing of corrected drawings so as to obviate the objection.**

Claims 1 and 2 have been amended by the preliminary amendment filed August 31, 2000.

Claims 1-16 are pending for examination.

The specification is objected because the first paragraph of the specification regarding the cross-reference information needs to be updated to reflect the relationship between this reissue application and the issued patent

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

The reissue oath or declaration filed August 31, 2000 complies with 37 CFR 1.63 and with 37 CFR 1.175.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject mater which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are readable on a genus of isolated naturally occurring promoters, synthetic promoters, or chimeric promoters whose transcriptional activity is activated by an Epstein-Barr Virus antigen (EBV antigen) or a papilloma virus antigen.

The specification at the time the invention was made only provides sufficient description of only one species of the chimeric promoter EBNA1-RE/TP1 (column 7).

However, the claims encompass a genus of naturally occurring, synthetic, or chimeric promoters that must possess the property of being able to be activated transcriptionally by any EBV antigen or any papilloma virus antigen. Since the claimed genus encompasses other chimeric sequences yet to be discovered, and since the disclosure only provides the disclosure of the chimeric promoter EBNA1-RE/TP1as the chimeric promoter module within the context of the claimed invention. Weighing all factors, 1) disclosure of only the chimeric promoter EBNA1-RE/TP1, 2) the breadth of the claim as reading on genomic regulatory sequences and man-made regulatory sequences yet to be discovered, and 3) No specific drawings and structures that would lead one skilled in the art to envision a representative number of species of chimeric promoter modules, one skilled in the art would not recognize from the disclosure that application was in possession of the genus of promoter sequences, which are essential features of the presently pending claims.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to:

A replication defective recombinant adenovirus comprising a heterologous DNA sequence under the control of the chimeric promoter EBNA1-RE/TP1 which is inducible by an Epstein-Barr virus antigen or by a papilloma virus antigen.

The specification is not enabling for any other claimed embodiment as embraced by the presently pending claims.

The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

When given their broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including unspecified regulatory sequences obtained from genomic sequences and/or man-made synthesis. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of nucleic acid elements as recited in the claims, particularly in view of the reasons set forth above, one skilled in the art would not known how to make and use the claimed invention as generically so that it would operate as intended.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
The recitations of "An adenovirus according to claim 1", "a replication defective recombinant adenovirus according to claim 1", and "A composition according to claim 12" are indefinite because it is not apparent as to what exactly the breadth of "An" that was chosen form the adenovirus according to claim 1, nor is it apparent as to how "a composition" is intended to be claimed from the composition according to claim 12. A change from the recitations to -- The adenovirus according to claim 1 --, -- the replication defective recombinant adenovirus according to claim 1 --, or -- the composition according to claim 1 – is suggested.

In claim 14, the "viral promoter" lacks an antecedent basis from the base claim 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 9-13, 15 and 16 are rejected under 35 USC 102(b) as being anticipated by WO 93/19191 (translation copy also enclosed and referred as Haddada *et al.*), as evidenced by Phelps *et al.* (J. Virol, 65, 12, 1991, pp. 6922-30) or Sample *et al.* (The Epstein-Barr Virus and Associated Diseases, Vol. 225, pp. 165-168, 1993)

Haddada *et al.* teaches a composition comprising an effective amount of replication defective adenovirus vector particles for cell transfection, wherein the adenovirus particle comprising a replication defective adenovirus vector comprising the adenovirus E2 early promoter and any anti-tumor gene, *e.g.*, page 5 through page 6, page 17 bridging page 18. Pharmaceutically acceptable carriers are disclosure on page 10. Host cells comprising the vector also disclosed on page 11. While Haddada *et al.* does not teach that the adenovirus E2 early promoter can be activated by an EBNA2 of Epstein-Bar virus (EBV) or by a papilloma virus antigen. However, as evidenced by Phelps, which teaches that the E2 early promoter is activated by a human papilomavirus E7 antigen (entire disclosure), and as evidenced by Sample *et al.*, which teaches that EBNA2 of EBV can activate the activity of an adenovirus E2 promoter via E2 factor binding sites, the transcriptional activity of the adenovirus E2 promoter contained in the adenovirus vector of Haddada *et al.* would necessarily exhibit the activity of being able to be activated by EBNA2 of EBV or by a human papilomavirus E7 antigen.

Thus, claims, embracing replication defective adenovirus vector comprising a replication defective adenovirus vector comprising an expression signal sequence, which is inducible or activated by a papilloma virus antigen or EBNA2 of EBV, are anticipated by the teachings of the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is

advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, and 7-8 are rejected under 35 USC 103(a) as being unpatentable over Haddada *et al.*, as evidenced by Phelps *et al.* (J. Virol, 65, 12, 1991, pp. 6922-30) or Sample *et al.* (The Epstein-Barr Virus and Associated Diseases, Vol. 225, pp. 165-168, 1993, and further in view of by Woo *et al.* (US Pat No. 5,631,236).

The rejection of the base claim 1 as being anticipated by Haddada *et al.*, as evidenced by Phelps *et al.* and Sample *et al.* is applied here as indicated above. To the extent that Haddada *et al.* does not teach the use of a Hsv-Tk gene (thymidine kinase gene) as the anti-tumor gene that activates acyclovir or ganciclovir so as to kill tumor cells, Woo. teaches a composition comprising an effective amount of replication defective adenovirus vector particles for cell transfection, wherein the adenovirus particle comprising a replication defective adenovirus vector comprising an anti-tumor Hsv-tk (thymidine kinase gene) gene which codes for a product that activates ganciclovir or acyclovir for killing tumor cells (columns 2 and 3).

It would have been obvious for one of ordinary skill in the art to have employed the Hsv-Tk gene as the anti-tumor gene(s) in the adenoviral vector of Haddada *et al.* The skilled artisan would have been motivated to employ the Hsv-Tk gene in the adenovirus vector so as provide a combination effect together with toxic drugs such as ganciclovir or acyclovir. One also has been motivated to use the Hsv-Tk gene in the adenovirus vector of Haddada *et al.* because Woo *et al.* teaches that the Hsv-Tk gene is an anti-tumor gene that is effectively with acyclovir or ganciclovir to kill tumor cells.

Thus, the claimed invention as a whole is *prima facie* obvious.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER